[4910-13]

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 121

[Docket No.: FAA-2013-1013; Amdt. No. 121-367]

RIN 2120–AK-35

Use of Additional Portable Oxygen Concentrators on Board Aircraft

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Immediately adopted final rule

SUMMARY: This action amends the FAA's rules for permitting use of portable oxygen concentrator (POC) devices on board aircraft, provided certain conditions in the SFAR are met. This action is necessary to allow all POC devices deemed acceptable by the FAA for use in air commerce to be available to the traveling public in need of oxygen therapy. Passengers will be able to carry these devices on board the aircraft and use them with the approval of the aircraft operator.

DATES: Effective [INSERT 15 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: For technical questions concerning this action, contact DK Deaderick, Air Transportation Division, AFS-200, Flight Standards Service, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone 202-267-8166; e-mail DK.Deaderick@faa.gov

For legal questions concerning this action, contact Robert H. Frenzel, Manager, Operations Law Branch, Office of the Chief Counsel, Regulations Division (AGC-220),

Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone 202-267-3073; e-mail Robert.Frenzel@faa.gov.

SUPPLEMENTARY INFORMATION:

Good Cause for Immediate Adoption

Section 553 of the Administrative Procedure Act, 5 U.S.C. 553(b)(3)(B), provides that, when an agency for good cause finds that notice and public procedure are impracticable, unnecessary, or contrary to the public interest, the agency may issue a rule without providing notice and an opportunity for public comment. We have determined that there is good cause for making the rule final without prior proposal and opportunity for comment because the issues related to the use of POC devices on board aircraft have already been discussed as part of an earlier rulemaking. More specifically, on July 14, 2004, the FAA issued a notice of proposed rulemaking (NPRM) on the use of POC devices on board aircraft (69 FR 42324). Then, on July 12, 2005, after reviewing public comments received, the FAA published Special Federal Aviation Regulation 106 (SFAR 106) entitled, "Use of Certain Portable Oxygen Concentrator Devices on Board Aircraft" (70 FR 40156). Therefore, the FAA has determined that notice and public comment are unnecessary.

Moreover, pursuant to 5 U.S.C. 553(d)(3), we find that good cause exists for making this rule effective in less than 30 days. This rule is being made effective 15 calendar days after its publication in the **Federal Register** to prevent unnecessary delay of additional POC devices for use on board aircraft by airlines while still providing airlines adequate notice and time to ensure the devices can be used safely on board aircraft. We believe, based on information the Department has received from airlines, that

fifteen calendar days is sufficient amount of time for an airline to ensure that an FAA-approved POC device does not cause interference with avionics systems on that carrier's aircraft and convey this information to the appropriate airline personnel in order to accept these devices on board aircraft for use by passengers who need medical oxygen therapy for air travel. As such, the FAA believes that good cause exists for making this rule effective 15 calendar days after its publication in the Federal Register.

Authority for this Rulemaking

The FAA's authority to issue rules on aviation safety is found in Title 49 of the United States Code (U.S.C.). This rulemaking is promulgated under the authority described in 49 U.S.C. 106(f), which vests final authority in the Administrator for carrying out all functions, powers, and duties of the administration relating to the promulgation of regulations and rules, and section 44701(a)(5), which requires the Administrator to promulgate regulations and minimum standards for other practices, methods, and procedures necessary for safety in air commerce and national security.

I. Overview of the Immediately Adopted Final Rule

This action amends SFAR 106 and permits the use of additional POC devices on board aircraft. Specifically, the FAA is adding the use of SeQual Technologies's eQuinox (model 4000) and Oxywell (Model 4000), and VBOX Inc.'s Trooper on the list of POC devices authorized for use in air commerce. The FAA has reviewed these devices and accepted the documentation provided by the manufacturer. After reviewing the applicable Food and Drug Administration (FDA) safety standards and the Pipeline and Hazardous Materials Safety Administration (PHMSA) findings, the devices were determined by the FAA to be acceptable for use in air commerce.

II. Background

A. Statement of the Problem

When SFAR 106 was published, the FAA committed to establishing a single performance standard for all POCs so the regulations would not apply to specific manufacturers and models of device. Whenever possible, the FAA tries to regulate by creating performance-based standards. In the case of SFAR 106, the most efficient way to serve both the passenger and the aircraft operator was to allow the use of the devices determined to be acceptable by the FAA in SFAR 106 in a special temporary regulation.

As the FAA stated in the preamble discussion of the final rule that established SFAR 106, "while we are committed to developing a performance-based standard for all future POCs, we do not want to prematurely develop standards that have the effect of stifling new technology of which we are unaware." The FAA developed and published SFAR 106 so passengers who otherwise could not fly could do so with an affordable alternative to what existed before SFAR 106 was published.

The FAA continues to pursue the performance-based standard for all POC devices. This process is time-consuming, and the FAA intends to publish a notice in the **Federal Register** and offer the public a chance to comment on the proposal when it is complete. In the meantime, manufacturers continue to create new and innovative POC devices, and manufacturers have requested that their products also be included as acceptable POC devices in SFAR 106. SeQual Technologies, Inc. and VBOX, Inc. have submitted requests for approval and addition to SFAR 106, with all required documentation for their POC devices, to the FAA.

B. Related Actions

On July 12, 2005, the FAA published SFAR 106 entitled, "Use of Certain Portable Oxygen Concentrator Devices Onboard Aircraft" (70 FR 40156). SFAR 106 is the result of a notice the FAA published on July 14, 2004 (69 FR 42324) to address the needs of passengers who must travel with medical oxygen. Before publication of SFAR 106, passengers in need of medical oxygen during air transportation faced many obstacles when requesting service. Many aircraft operators did not provide medical oxygen service aboard flights, and those that did often provided service at a price that travelers could not afford. Coordinating service between operators and suppliers at airports was also difficult, and passengers frequently chose not to fly because of these difficulties.

SFAR 106 permits passengers to carry-on and use certain POC devices on board aircraft, if the aircraft operator ensures that the conditions specified in the SFAR 106 for their use are met. The POC devices initially determined acceptable for use in SFAR 106, published July 14, 2005, were AirSep Corporation's LifeStyle and Inogen, Inc.'s Inogen One. SFAR 106 has been amended six times to allow passengers to use additional devices.

III. Discussion of the Immediately Adopted Rule

New medical oxygen technologies (POC devices) approved by the FDA reduce the risks typically associated with compressed oxygen and provide a safe alternative for passengers who need oxygen therapy. Numerous manufacturers have developed small POC devices that work by separating oxygen from nitrogen and other gases contained in ambient air and dispensing it in concentrated form to the user with an oxygen concentration of about 90%. The POC devices operate using either rechargeable batteries or, if the aircraft operator obtains approval from the FAA, aircraft electrical power.

Additionally, as stated in Section 2 of SFAR 106, no covered device may contain hazardous materials as determined by PHMSA (written documentation necessary), and each device must also be regulated by the FDA.

This immediately adopted amendment to SFAR 106 is adding three additional POC devices, thus, increasing the number of options for aircraft passengers to carry on and use on board aircraft. The FAA is adding SeQual Technologies, Inc.'s eQuinox Oxygen System (model 4000) and Oxywell Oxygen System (model 4000), as well as VBOX, Inc.'s Trooper device to the list of POC devices that may be carried on and used by a passenger on board an aircraft. Each manufacturer has included technical specifications for their devices in each request for approval, as well as the required documentation from PHMSA and the FDA.

SFAR 106 is an enabling rule, which means that no aircraft operator is required to allow passengers to operate POC devices on board. If an aircraft operator chooses to allow a passenger to operate these devices, SFAR 106 enables such action, provided that the SFAR 106 conditions are met.

IV. Regulatory Notices and Analyses

A. Regulatory Evaluation

Changes to Federal regulations must undergo several economic analyses. First, Executive Order 12866 directs that each Federal agency shall propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 (Pub. L. 96-354) requires agencies to analyze the economic impact of regulatory changes on small entities. Third, the Trade Agreements Act of 1979 (Pub. L. 96-39) prohibits agencies from setting

standards that create unnecessary obstacles to the foreign commerce of the United States. In developing U.S. standards, this Trade Act requires agencies to consider international standards and, where appropriate, that they be the basis of U.S. standards. Fourth, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4) requires agencies to prepare a written assessment of the costs, benefits, and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million or more annually (adjusted for inflation with base year of 1995). This portion of the preamble summarizes the FAA's analysis of the economic impacts of this final rule.

Department of Transportation Order DOT 2100.5 prescribes policies and procedures for simplification, analysis, and review of regulations. If the expected cost impact is so minimal that a proposed or final rule does not warrant a full evaluation, this order permits that a statement to that effect and the basis for it be included in the preamble if a full regulatory evaluation of the cost and benefits is not prepared. Such a determination has been made for this final rule. The reasoning for this determination follows:

This action amends SFAR 106 to allow for the use of additional POC devices on board aircraft, provided certain conditions in the SFAR are met. This action is necessary to allow additional POC devices deemed acceptable by the FAA to be available to the traveling public in need of oxygen therapy, for use in air commerce. As the rule increases the number of acceptable POC devices on board aircraft, the rule does not increase costs and provides additional benefits. The FAA has, therefore, determined that this final rule is not a “significant regulatory action” as defined in section 3(f) of Executive Order

12866, and is not “significant” as defined in DOT's Regulatory Policies and Procedures.

B. Regulatory Flexibility Determination

The Regulatory Flexibility Act of 1980 (Pub. L. 96-354) (RFA) establishes “as a principle of regulatory issuance that agencies shall endeavor, consistent with the objectives of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation. To achieve this principle, agencies are required to “solicit and consider flexible regulatory proposals and to explain the rationale for their actions to assure that such proposals are given serious consideration.” The RFA covers a wide-range of small entities, including small businesses, not-for-profit organizations, and small governmental jurisdictions.

Agencies must perform a review to determine whether a rule will have a significant economic impact on a substantial number of small entities. If the agency determines that it will, the agency must prepare a regulatory flexibility analysis as described in the RFA.

However, if an agency determines that a rule is not expected to have a significant economic impact on a substantial number of small entities, section 605(b) of the RFA provides that the head of the agency may so certify and a regulatory flexibility analysis is not required. The certification must include a statement providing the factual basis for this determination, and the reasoning should be clear.

As this final rule enables additional POC devices to be carried on board aircraft, the rule provides benefits at minimal costs for passengers and minimal implementation costs for all business entities.

Therefore, as provided in section 605(b), the head of the FAA certifies that this rulemaking will not result in a significant economic impact on a substantial number of small entities.

C. International Trade Impact Assessment

The Trade Agreements Act of 1979 (Public Law 96-39), as amended by the Uruguay Round Agreements Act (Public Law 103-465), prohibits Federal agencies from establishing standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Pursuant to these Acts, the establishment of standards is not considered an unnecessary obstacle to the foreign commerce of the United States, so long as the standard has a legitimate domestic objective, such the protection of safety, and does not operate in a manner that excludes imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards. The FAA has assessed the potential effect of this immediately adopted final rule and determined that it will have only a domestic impact and therefore will not create unnecessary obstacles to the foreign commerce of the United States.

D. Unfunded Mandates Assessment

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4) requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in an expenditure of $100 million or more (in 1995 dollars) in any one year by State, local, and tribal governments, in the aggregate, or by the private sector; such a mandate is deemed to be a “significant regulatory action.” The FAA currently uses an inflation-adjusted value of $143.1 million

in lieu of $100 million. This final rule does not contain such a mandate; therefore, the requirements of Title II of the Act do not apply.

E. Paperwork Reduction

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires that the FAA consider the impact of paperwork and other information collection burdens imposed on the public. According to the 1995 amendments to the Paperwork Reduction Act (5 CFR 1320.8(b)(2)(vi)), an agency may not collect or sponsor the collection of information, nor may it impose an information collection requirement unless it displays a currently valid Office of Management and Budget (OMB) control number.

Information collection requirements associated with this final rule have been approved previously by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) and have been assigned OMB Control Number 2120-0702. This final rule requires that if a passenger carries a POC device on board the aircraft with the intent to use it during the flight, he or she must inform the pilot in command of that flight. Additionally, the passenger who plans to use the device must provide a written statement signed by a licensed physician that verifies the passenger's ability to operate the device, respond to any alarms, the extent to which the passenger must use the POC (all or a portion of the flight), and prescribes the maximum oxygen flow rate. The Paperwork Reduction Act paragraph in the final rule that established SFAR 106 still applies to this amendment. The availability of a new POC device will likely increase the availability and options for a passenger in need of oxygen therapy, but the paperwork burden discussed in the original final rule is unchanged. Therefore, the OMB Control Number associated with this collection remains

2120-0702.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

F. International Compatibility and Cooperation

In keeping with U.S. obligations under the Convention on International Civil Aviation, it is FAA policy to conform to International Civil Aviation Organization (ICAO) Standards and Recommended Practices to the maximum extent practicable. The FAA has determined that there are no ICAO Standards and Recommended Practices that correspond to these regulations.

Executive Order 13609, Promoting International Regulatory Cooperation, promotes international regulatory cooperation to meet shared challenges involving health, safety, labor, security, environmental, and other issues and to reduce, eliminate or prevent unnecessary differences in regulatory requirements. The FAA has analyzed this action under the policies and agency responsibilities of Executive Order 13609, and has determined that this action would have no effect on international regulatory cooperation.

G. Environmental Analysis

FAA Order 1050.1E identifies FAA actions that are categorically excluded from preparation of an environmental assessment or environmental impact statement under the National Environmental Policy Act in the absence of extraordinary circumstances. The FAA has determined this rulemaking action qualifies for the categorical exclusion identified in paragraph 312f and involves no extraordinary circumstances.

V. Executive Order Determinations

A. Executive Order 13132, Federalism

The FAA has analyzed this immediately adopted final rule under the principles and criteria of Executive Order 13132, Federalism. The agency determined that this action will not have a substantial direct effect on the States, or the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government, and, therefore, does not have Federalism implications.

B. Executive Order 13211, Regulations that Significantly Affect Energy Supply, Distribution, or Use

The FAA analyzed this immediately adopted final rule under Executive Order 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use (May 18, 2001). The agency has determined that it is not a "significant energy action" under the executive order and it is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

VI. How To Obtain Additional Information

A. Rulemaking Documents

An electronic copy of a rulemaking document may be obtained by using the Internet —

1. Search the Federal eRulemaking Portal (http://www.regulations.gov);
2. Visit the FAA's Regulations and Policies Web page at http://www.faa.gov/regulations_policies/ or
3. Access the Government Printing Office's Web page at http://www.gpo.gov/fdsys/.

Copies may also be obtained by sending a request (identified by notice, amendment, or docket number of this rulemaking) to the Federal Aviation Administration, Office of Rulemaking, ARM-1, 800 Independence Avenue SW., Washington, DC 20591, or by calling (202) 267-9680.

B. Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996 requires FAA to comply with small entity requests for information or advice about compliance with statutes and regulations within its jurisdiction. A small entity with questions regarding this document, may contact its local FAA official, or the person listed under the FOR FURTHER INFORMATION CONTACT heading at the beginning of the preamble. To find out more about SBREFA on the Internet, visit http://www.faa.gov/regulations_policies/rulemaking/sbre_act/.

List of Subjects in 14 CFR Part 121

Air carriers, Aircraft, Airmen, Reporting and recordkeeping requirements.

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends SFAR No. 106 to Chapter I of title 14, Code of Federal Regulations as follows:

PART 121--OPERATING REQUIREMENTS: DOMESTIC, FLAG, AND SUPPLEMENTAL OPERATIONS

1. The authority citation for part 121 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40113, 40119, 41706, 44101, 44701-44702, 44705, 44709-44711, 44713, 44716-44717, 44722, 46105.

2. Amend SFAR 106 by revising sections 2 and 3(a) introductory text to read as

follows:

Special Federal Aviation Regulation 106—Rules for use of Portable Oxygen Concentrator Systems on Board Aircraft

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Section 2. Definitions—For the purposes of this SFAR the following definitions apply: Portable Oxygen Concentrator: means the AirSep FreeStyle, AirSep LifeStyle, AirSep Focus, AirSep Freestyle 5, Delphi RS-00400, DeVilbiss Healthcare iGo, Inogen One, Inogen One G2, Inogen One G3, Inova Labs LifeChoice, Inova Labs LifeChoice Activox, International Biophysics LifeChoice, Invacare XPO2, Invacare Solo2, Oxlife Independence Oxygen Concentrator, Oxus RS-00400, Precision Medical EasyPulse, Respironics EverGo, Respironics SimplyGo, SeQual Eclipse, SeQual eQuinox Oxygen System (model 4000), SeQual Oxywell Oxygen System (model 4000), SeQual SAROS and VBOX Trooper Oxygen Concentrator medical device units as long as those medical device units: (1) Do not contain hazardous materials as determined by the Pipeline and Hazardous Materials Safety Administration; (2) are also regulated by the Food and Drug Administration; and (3) assist a user of medical oxygen under a doctor's care. These units perform by separating oxygen from nitrogen and other gases contained in ambient air and dispensing it in concentrated form to the user.

Section 3. Operating Requirements—

(a) No person may use and no aircraft operator may allow the use of any portable oxygen concentrator device, except the AirSep FreeStyle, AirSep LifeStyle, AirSep Focus, AirSep FreeStyle 5, Delphi RS-00400, DeVilbiss Healthcare iGo, Inogen One, Inogen One G2, Inogen One G3, Inova Labs LifeChoice, Inova Labs LifeChoice Activox,

International Biophysics LifeChoice, Invacare XPO2, Invacare Solo2, Oxlife Independence Oxygen Concentrator, Oxus RS-00400, Precision Medical EasyPulse, Respironics EverGo, Respironics SimplyGo, SeQual Eclipse, SeQual eQuinox Oxygen System (model 4000), SeQual Oxywell Oxygen System (model 4000), SeQual SAROS and VBOX Trooper Portable Oxygen Concentrator units. These units may be carried on and used by a passenger on board an aircraft provided the aircraft operator ensures that the following conditions are satisfied:

* * * * *

Issued under authority provided by 49 U.S.C. 106(f) and 44701(a)(5) in Washington, DC, on December 23, 2013.

Michael P. Huerta

Administrator

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